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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,012	06/13/2001	Edward I. Ginns	015280-248120US	8624

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/881,012

Applicant(s)

GINNS ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 03 March 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1,6-8,11,12 and 15-23.Claim(s) withdrawn from consideration: 13,14 and 27.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet



Continuation of 5. does NOT place the application in condition for allowance.

The response argues that the claims are drawn to screening methods of genotypes to determine whether a genotype is associated with increased bipolar affective disorder. The claims as written do not make it clear that the claim is drawn to a screening method. The claim requires using a marker associated with resistance to bipolar disorder. Therefore it is not clear that this is screening for markers associated with resistance to bipolar affective disorder. Applicant argues selection of variants is routine. This is not correct because it is entirely unpredictable if there are variants. In fact, Applicant is attempting to claim this subject matter because it is not routine. It is entirely unpredictable and inventive whether any particular microsatellite marker, translocation, mutation, deletion, splice variant or polymorphism is associated with BPAD. In particular, this unpredictability, combined with the other factors, supports a conclusion of undue experimentation.

Unlike the simple screening assay in Wands itself, where experimental success was assured so long as sufficient resources were expended, since eventually an antibody producing cell would be isolated, here there is no assurance or even likelihood of success, since there is no reason to believe that other polymorphisms necessarily exist which have the desired correlation. At the time of the invention, it is speculative and without evidentiary basis to predict if there will be any results from the screening for additional polymorphisms, unlike Wands where it is not only possible but expected that results will be achieved. Here, there is no expectation that other polymorphisms associated with BPAD will be found. The claimed invention is an idea for future investigation or research. The exact purpose of the method is to determine whether additional genotypes are associated with BPAD.

It is acknowledged that there is at least one marker within each of the claimed regions which is correlated, however there are also several markers which are not correlated. It is noted that each of these regions is extremely large. For example the region on chromosome 4 is a range of 33.3cM and 42.8cM. These are much larger than the attorney arguments stating that "one would reasonably expect that marker located at about 10cM from a marker would be linked to that marker. It is noted that this is attorney arguments. The submission of the post filing date article to try and establish the current practice in the field is not appropriate (page 10 of response). The enablement of an invention is determined at the time of filing. The instant filing date is 1997. Therefore, the state of the art in 2003 is not at the time the invention was made. As provided by MPEP 2164.05, "To overcome a prima facie case of lack of enablement, applicant must demonstrate by argument and/or evidence that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of filing."

The response asserts that the fact that markers within a region of interest may not appear significantly correlated with BPAD does not cast doubt on the conclusion that the region is correlated with BPAD. This argument has been thoroughly reviewed, a found persuasive based upon further review of the art and the arguments.

The response correctly argues that the specification, not the claims, provides the general method for screening individuals for particular predispositions. The basic method is well known method for comparing and determining whether an association exists, however, the outcome of each of the markers encompassed by the claims is unpredictable and undue experimentation. Just because the method can be performed does not enable the skilled artisan to make the specific genotypes. The nature of alleles and markers are such that the general knowledge in the art concerning one allele does not provide any indication of how the structure of one alleles is representative of unknown alleles. They are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others and the enablement of the others.

With respect to the description issue, the specification fails to provide any deletions, translocations, SNPs, or mutations which are within the scope of the genus. While the response does not appear to focus on the description issue. The specification has not described and was not in possession of a representative number of markers which were linked to a locus associated with resistance to bipolar disorder in the 33cm region of D4S431 and D4S404.

Continuation of 10. Other: Upon review of the formal matters of the application, there is no clear indication of the relationship of the application to 08/827,568 in the first line of the specification or the ADS sheet. Correction is required by 37 CFR 1.78(a)(2) and 1.76. A specific relationship between applications and the status of the applications is required by the provision. It is further noted that Failure to timely submit the reference required by 37 CFR 1.78(a)(2)(i) is considered a waiver of any benefit claim under 35 U.S.C. § 120, 121 or 365(c) unless a petition to accept an unintentionally delayed claim under 37 CFR 1.78(a)(3), the surcharge set forth in 37 CFR 1.17(t), and the required reference, including the relationship of the applications (unless previously submitted) are filed. For example, if a benefit claim is submitted without the specific relationship between the nonprovisional applications before the expiration of the period, and the specific relationship between the nonprovisional applications is subsequently submitted after the expiration of the period, a petition and the surcharge would be required.